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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/496,231	02/01/00	HUBBELL J	50154/002002

HM12/0112

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EXAMINER	
HOUTTEMAN, S	
ART UNIT	**PAPER NUMBER**
1656	11

DATE MAILED: 01/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/496,231	Hubbel et al.
Examiner	**Group Art Unit**
Scott Houtteman	1656

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-50* is/are pending in the applicat

Of the above, claim(s) *20-50* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-19* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper ~~No(s)~~ Filed 7/31/00

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. I. Claims 1-19, drawn to methods of making biomolecules, classified in class 536, subclass 25.3.

II. Claims 20-38, drawn to biomolecules, classified in class 536, subclass 23.3.

III. Claims 39-43, drawn to methods of delivery, classified in class 514, subclass 44.

IV. Claims 44-46, drawn to methods of tissue regeneration, classified in class 424, subclass 198.1.

V. Claim 47, drawn to a method of preventing adhesions, classified in class 514, subclass 2.

VII. Claims 49 and 49, drawn to methods of fluid/gas flow sealing, classified in class 424, subclass 94.1.

VIII. Claim 50, drawn to a method of encapsulation, classified in class 427, subclass 338.

2. The inventions are distinct, each from the other because of the following reasons: The biomolecules of Group II relate to the methods of groups I and III-VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this case the biomolecules and be used in the materially different process of groups I and III-VII.

3. The processes of groups I and III-VII are distinct. They have different reagents, different steps and result in different end products.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Applicant returned the Examiner's call on 12/18/00 and elected Group I, claims 1-19 without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyethylene glycol polymers, does not reasonably provide enablement for the generic class of methods of combing two or more "precursors" by nucleophilic addition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 1-19 read on any polymers constructed by nucleophilic addition. A nucleophile is any organic group that can be an electron donor. Thus the claims encompass such diverse compounds and carbohydrates, nucleic acids and protons.

The specification, in contrast, offers only relatively narrow guidelines in making and using only one class of nucleophile, those used to construct PEG derivatives used as hydrogels.

Furthermore, Hern et al., J. Biomed. Mater. Res. 39:266-76, 1988 (Hern) teaches that PEG has several properties which are essential for hydrogels. The compounds must not stick to cells, must be biodegradable and must be able to be synthesized in vivo. See Hern p. 266.

Lacking any further guidance from the specification the skilled artisan must perform the undue experimentation of developing synthesis protocols, testing cell adhesion, biodegradability etc. of the resulting polymers. Since the claims are not limited to uses of any kind, the skilled artisan must also experiment to uncover a reasonable use for these compounds.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

9. Claims 1-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hern.

Hern teaches the two precursors for PEG, including a nucleophile. See Hern p. 266. Hern also teaches the claimed strong nucleophiles comprising thiol groups, self selective reactions, acrylate unsaturated group, three functionalities , an adhesion site, synthesis within cells or tissues. See, for example, Hern, p. 267, Fig. 1; p. 268, col. 2; "acrylation" p. 269, col. 2.

10. The claims differ from Hern in the recitation "wherein the functionality of each component is at least two." However, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use monomers having two functionalities for the reason, explicitly set forth in Hern, of promoting polymerization.

11. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Technology Center 1600 Fax numbers are (703) 305-3014 and 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
December 18, 2000

SCOTT W. HOUTTEMAN
PRIMARY EXAMINER